

Terms of Reference and Rules of Procedure **Clinical Trials Subcommittee**



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1 ESTABLISHMENT

- 1.1 The Clinical Trials Subcommittee is established by the Advisory Committee on Human Medicines (ACHM).

2 MANDATE

- 2.1 The subcommittee reviews applications to conduct or to amend clinical trials on medicinal products for human use, on the basis of their quality, safety and efficacy.
- 2.2 The subcommittee advises the Health Products Regulatory Authority (the Authority) on the suitability of clinical trial applications for authorisation.
- 2.3 The subcommittee advises the ACHM and the Authority on matters referred to it relating to clinical trials using medicinal products for human use.
- 2.4 Where the subcommittee advises the Authority, such advice will not be subject to confirmation by the ACHM.

3 COMPOSITION

- 3.1 The subcommittee consists of members appointed by the ACHM for a period not exceeding the duration of the term of office of the ACHM and any person appointed to it by the Minister for Health.
- 3.2 Members of the subcommittee are paid allowances for expenses as the Authority may, with the consent of the Minister for Health and the Minister for Finance, determine.

4 CHAIRPERSON

- 4.1 The Chairperson is appointed by the ACHM from among the members of the subcommittee. The Chairperson is a member of the ACHM.
- 4.2 The Chairperson is responsible for the efficient conduct of the business of the subcommittee, in particular by:
- planning the work of the committee together with the secretary to the committee,
 - monitoring, together with the secretary to the committee, that the rules of procedure are respected,
 - ensuring that at the beginning of each meeting, any potential conflict of interest is declared regarding any particular item to be discussed by the committee,

- aiming to achieve consensus on issues discussed by the committee,
- ensuring, together with the committee and the secretary to the committee, the regulatory and scientific consistency of the committee's recommendations, and
- reporting on the activities of the committee as appropriate.

5 MEETINGS

- 5.1 Meetings are held with sufficient frequency to enable the subcommittee to carry out its functions. If appropriate, the Chairperson will consult with officers of the Authority in determining the frequency of meetings.
- 5.2 Members of the committee may participate in meetings by telephone, teleconference or videoconference. Members so participating are considered to be present at the meeting. The Secretary to the Authority also attends the meetings.
- 5.3 Meetings are chaired by the Chairperson. In his/her absence, an acting Chairperson is appointed from among the members of the committee.
- 5.4 The subcommittee may act in the absence of one or more members. If members cannot attend all or part of a meeting, they should notify the secretary to the committee in advance of the meeting.
- 5.5 The agenda is established by the Chairperson and if appropriate, in consultation with the ACHM or members of the staff of the Authority, and the secretary to the committee. It is circulated with related papers in advance of the meeting.
- 5.6 Each member of the subcommittee present has one vote. Decisions are made by consensus or by a majority of the votes of the members present. If there is an equal division of votes, the Chairperson has a casting vote.
- 5.7 Any employee or other person may be invited to attend for particular items at the discretion of the Chairperson but they are not entitled to vote.

6 MINUTES OF MEETINGS

- 6.1 Minutes of each meeting are prepared by the secretary to the committee.
- 6.2 The minutes indicate the names of attendees, and in respect of each item on the agenda:
- the documents submitted to the subcommittee,
 - a summary record of the proceedings,
 - the decisions taken or the conclusions reached by the subcommittee.

- 6.3 Draft minutes are sent to members before the next meeting. They are adopted at the following meeting and signed by the Chairperson.

7 REPORTING

- 7.1 The outcome of meetings is reported to the ACHM. The Chairperson will inform the ACHM of significant issues discussed at the subcommittee and, where necessary, present recommendations for the ACHM's consideration and decision.

8 GUARANTEES OF INDEPENDENCE AND CODE OF CONDUCT

- 8.1 The names of the subcommittee members and their professional qualifications are made public.
- 8.2 Members of the subcommittee will make an annual declaration of financial or other beneficiary interest in any industry regulated by the Authority.
- 8.3 At each meeting, members will declare any financial or other beneficiary interest in any agenda item. When a member is unable to participate in a meeting due to a conflict of interest, he or she must inform the secretary to the committee in advance of the meeting in writing. They will withdraw from the meeting while the item is considered and will not vote or act as a member in relation to it.
- 8.4 Members of the subcommittee will abide by the Code of Conduct approved by the Authority.
- 8.5 Members of the subcommittee are required not to disclose information received by them while performing their duties, even after their duties have ceased.

9 LEGAL ISSUES

- 9.1 The subcommittee may avail of legal advice from the Authority's solicitor on any issues which may arise.

10 GENERAL PROVISIONS

- 10.1 These terms of reference and rules of procedure are approved by the ACHM and the subcommittee, and are made public.